RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	cyclosporine
Policy Number:	RxA.466
Drug(s) Applied:	Restasis®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Cyclosporine ophthalmic emulsion (Restasis®) is a topical calcineurin inhibitor immunosuppressant. Ophthalmic cyclosporine is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cyclosporine (Restasis®)	Moderate to severe keratoconjunctivitis sicca	1 drop twice daily in each eye, approximately 12 hours apart	2 drops/day in each eye; 60 vials/30 days

Dosage Forms

- Single use vial: 0.05%, 0.4 mL each in 30 vials/tray and 60 vials/tray
- Multidose bottle: 0.05%, 5.5 mL total

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Keratoconjunctivitis Sicca (must meet all):

1. Diagnosis of keratoconjunctivitis sicca with suppressed tear production due to ocular inflammation;
2. Age 16 years of age or older;
3. Failure of artificial tears at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of at least one (1) ophthalmic anti-inflammatory agent (see Appendix B for examples) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed 60 vials per 30 days.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy

A. Keratoconjunctivitis Sicca (must meet all):

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. increased tear production);
3. If request is for a dose increase, request does not exceed 60 vials per 30 days.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BID: Twice daily
FDA: Food and Drug Administration
NSAIDs: Non-Steroidal Anti-Inflammatory Drugs
QID: Four times daily

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements. Note: Ophthalmic NSAIDs are not indicated.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
artificial tears (e.g., Visine dry eye relief)	1 to 2 drops in affected eye(s) BID or QID	various
ophthalmic anti-inflammatory agents for keratoconjunctivitis sicca (e.g., loteprednol etabonate)	1 to 2 drops in each eye BID to QID for up to 2 weeks	various

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Active ocular infections;
  - hypersensitivity to cyclosporine or any of the ingredients in the formulation.

- Boxed warning(s):
  - None

APPENDIX D: General Information

- Artificial tears are the standard therapy for all severity of dry eyes.
- Ophthalmic cyclosporine is likely to be given in conjunction with artificial tears.
- Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.
- Emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

References

1. Restasis Prescribing Information. Irvine, CA: Allergan, Inc.; July 2017. Available at: https://www.restasis.com/. Accessed October 6, 2020.
2. The International Dry Eye Workshop. Ocul Surf. 2007; 5(2):65:204. Accessed October 6, 2020.
3. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. Chicago, IL: American Academy of Ophthalmology; November 2018. Available at: www.aao.org/ppp. Accessed October 6, 2020.
4. Restasis. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 6, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy was reviewed 1. Policy formatting updated. 2. Policy updated to all lines of business. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Approval length for commercial line of business updated to 12 months. 5. Verbiage for Appendix B was updated. 6. Reference were reviewed and updated.	10/06/2020	12/07/2020